



**New Jersey Department of Health
Governor's Council for Medical Research and Treatment of Autism
Meeting Minutes – December 3, 2012, 6pm – 9pm (ratified)**

Council Members Present

Elizabeth K. Bell, BS, volunteer and independent contractor with Autism Speaks,
Autism Organization Representative

Matthew Cortland, BA, Instructor, Teach for America, Public Member

Caroline Eggerding, M.D., Healthcare Organization Representative and Chairperson of the
Governor's Council for Medical Research and Treatment of Autism

Susan P. Evans, Ed.D., Education Program Specialist for Early Intervention Program,
Commissioner of Health Appointee

B. Madeleine Goldfarb, MA, Founder/Director of the Noah's Ark Children's Association,
Autism Organization Representative

Ketan Kansagra, M.D., FAAP, Children's Hospital of New Jersey at Newark Beth Israel Medical
Center, Academic Institution Representative

Gary Weitzen, BA, Executive Director, Parents of Autistic Children (POAC) Autism Services,
Organization Representative

Absent

Linda S. Meyer, Ed.D., MPA, BCBA-D Executive Director of Autism New Jersey, Autism
Organization Representative

Judah Zeigler, Senate President Appointee

NJ Department of Health (DOH) Attendees

Martin T. Zanna M.D., MPH
Acting Executive Director
Governor's Council for Medical Research and Treatment of Autism

Cynthia Kirchner, MPH
Director, Quality Improvement
Ethics Liaison for the DHSS

Linda N. Bocclair, M.Ed., MBA
Executive Assistant
Governor's Council for Medical Research and Treatment of Autism

Mary Ray, Contract Administrator 2
Governor's Council for Medical Research and Treatment of Autism
Commission on Brain Injury Research
Commission on Spinal Cord Research

Daphne Robinson, Ph.D., Consultant
Scientific Planning Consulting

Public Attendees

Jill Harris, Ph.D., Children's Specialized Hospital
Yvette Janvier, M.D., Children's Specialized Hospital
Audrey Mars, M.D., Hunterdon Medical Center
Mark Mintz, M.D., CNNH
Pnina Mintz, Ph.D., CNNH
Walter Zahorodny, Ph.D., UMDNJ

I. Welcome - Council Chairperson, Dr. Caroline Eggerding called the meeting to order at 6:10 PM and welcomed everyone.

II. Public Meetings Act Announcement- Dr. Eggerding read the Public Meetings Act, followed by roll call.

III. Approval of the September 10, 2012 Council Meeting Minutes

Dr. Eggerding called for a motion to approve the minutes. MOTION by Dr. Evans to approve the minutes was seconded by Mr. Weitzen.

MOTION to approve the minutes was passed with all in favor.

IV. Comments by Ms. Cynthia Kirchner

Ms. Cynthia Kirchner, Director of Quality Improvement and Ethics Liaison, Department of Health, provided an update on the current autism grant cycle and the availability of funds for autism research. She stated that nationally the economic climate is worrisome and New Jersey, as are many other states, is no exception. Council currently has a rather large fund balance that is intended to be used to fund autism research. Council will vote tonight to fund one or more

grants. In the event that not all funds are committed the Department will make a recommendation to Council to release another RFA awarding funds by the end of FY13 thus securing the funding for the Council's research grants. While this is an exciting time with two outstanding grants funded during the last grant cycle, it is also a challenging time given the new grant review process with its adherence to the highest standards in the evaluation and recommendations to fund only the highest quality clinical research.

A Council member asked if members of autism organizations can actively pursue their elected officials to advocate to retain the Council's funding. Ms. Kirchner confirmed that it is permissible for Council members to voice concern and opinions about retaining the funding for the purpose of implementing the mission as defined by the legislation. Dr. Eggerding commented, on behalf of the Council, appreciation for all the Department is doing to secure funding for the Council's grant programs.

Comments by Dr. Eggerding

Dr. Eggerding commented that the primary purpose of the meeting was to vote on the NJ ACE Clinical Research Program Site applications. Each application had been critiqued by three reviewers (primary, secondary and reader) and discussed and scored by all members of the Scientific Merit Review Panel, resulting in a very comprehensive evaluation process.

The intent of the current grant cycle was to award funding for up to two Clinical Research Program Sites given that only one Clinical Research Program Site was funded during the previous grant cycle. The NJ ACE Coordinating Center was also funded during the last grant cycle. In approving funding for the first Clinical Research Program Site Council held to the NIH criteria for excellence and accepted the recommendation of the Scientific Merit Review Panel to fund only those applications scoring 3 and below, with 1 being the highest score. Council held to the standard for various reasons and is encouraged to hold to those same standards in voting for the applications this time. It sends a strong message to not only the state of New Jersey but also nationally that we, as a state, have funding invested in autism research which is in and of itself an incredibly strong message on a national level and that the funding is going for research projects that have met the rigorous criteria for NIH quality grants.

Ms. Ray distributed the Conflict of Interest form to Council with a request to complete the form if any member had a conflict of interest with any of the applications. If there is a conflict the member must leave the room during the discussion of the application. There were no conflicts of interest reported by the Council members.

Dr. Eggerding requested that Dr. Zanna comment on the application review process. He described the levels of review starting with office review and followed by critiques of the applications by national experts (Scientific Merit Review Panel) in topical areas matched to the specific applications. The autism staff searched nationwide to recruit reviewers with appropriate expertise to serve on the Panel. The Scientific Merit Review Panel met via teleconference to discuss and score the applications. While the Panel was scheduled to meet in person, power outages and floods resulting from storm Sandy resulted in the need to hold the meeting via teleconference. Subsequent to the meeting Dr. Zanna consulted with the Scientific Advisory Committee (SAC) who, in turn, agreed with the recommendations of the Scientific Merit Review Panel.

Dr. Eggerding reminded members that for each application a motion will be made to accept the recommendation of the Scientific Merit Review Panel. Members can vote not to accept the recommendation of the Panel. The Panel members are nationally known experts in their respective fields. If Council values their recommendations and those of the Scientific Advisory Committee, who are also national experts in their fields, and the credibility of the entire review process, members should vote acceptance of the recommendations.

Dr. Eggerding commented that each application would be identified by the number of the application and the name of the institution.

CAUT13APS010

Dr. Eggerding called for a motion. MOTION by Ms. Goldfarb to approve the recommendation of the Scientific Merit Review Panel to fund CAUT13APS010 was seconded by Dr. Evans.

Discussion: This was the only program site that scored within the 1-3 range and recommended for funding by the Scientific Merit Review Panel. One member was pleased to see that the information from the first funded Program Site will be used by this applicant thus creating synergy between the two research projects. There were no further comments.

MOTION to approve the recommendation of the Scientific Merit Review Panel to fund CAUT13APS010 was passed with all in favor.

CAUT13APS001

Dr. Eggerding called for a motion. MOTION by Ms. Bell to approve the recommendation of the Scientific Merit Review Panel not to fund CAUT13APS001 was seconded by Dr. Evans.

Discussion- One member stated that he would vote to fund the application given that the one reviewer gave the application a score of “2”, well beyond the minimum score to award funding. The member stated that while there is a problem with the budget, the proposal is innovative and from a major institution. With oversight from the Coordinating Center he felt that it could be successful. One member requested information about the discussion among the members of the Scientific Merit Review Panel. Autism staff responded that one reviewer was in favor of the proposal and all other members pointed out serious issues with the project design and methodology. As a result, the project would not result in meaningful outcomes to the questions that they proposed to answer. Subsequent review by the Scientific Advisory Committee resulted in the Committee agreeing with the recommendation of the Review Panel not to fund this proposal and questioned how the one reviewer could have scored the application a “2”. A member asked if the applicant responded to the concerns expressed about their first application. While additional details were provided in the reapplication the Review Panel was still concerned with the flaws in the project design and methodology. Ms. Kirchner commented that the intent is to give those applicants who plan to apply to the new RFA the opportunity to address questions to the reviewers.

MOTION to approve the recommendation of the Scientific Merit Review Panel not to fund CAUT13APS001 was passed with six in favor and one no vote.

Ms. Kirchner commented that support will be provided for those applicants planning to reapply to the new RFA by referring questions from the applicants about the reviewers' critiques and notes from the reviewers' meeting to the respective reviewer(s). The intent is to clarify comments made by the reviewers and exchange any additional information to assist applicants with their new applications.

One member commented that clinical research is not always as clear as basic research and she encouraged office staff to do whatever they can to help applicants when they reapply. Dr. Eggerding commented that there may need to be interim steps to funding to adhere to Council's commitment to maintaining high standards.

CAUT13APS008

Dr. Eggerding called for a motion. MOTION by Ms. Goldfarb to approve the recommendation of the Scientific Merit Review Panel not to fund CAUT13APS008 was seconded by Dr. Kansagra.

Discussion- Autism staff commented that the SAC members thought that this application was closer to being fundable and that points were lost due to second project in this application. In addition, the first project takes longer and they agreed that the PI should collaborate with someone who is expert in the topical area.

MOTION to approve the recommendation of the Scientific Merit Review Panel not to fund CAUT13APS008 was passed with all in favor.

CAUT13APS014

Dr. Eggerding called for a motion. MOTION by Mr. Weitzen to approve the recommendation of the Scientific Merit Review Panel not to fund CAUT13APS014 was seconded by Ms. Goldfarb.

Discussion: One member commented that it was nice to see a new applicant from a healthcare system in addition to those who applied to the last RFA. The member commented that the applicant may be perfect for a pilot study given the next RFA will offer pilot projects along with program sites grants.

MOTION to approve the recommendation of the Scientific Merit Review Panel not to fund CAUT13APS014 was passed with all in favor.

CAUT13APS012

Dr. Eggerding called for a motion. MOTION by Dr. Evans to approve the recommendation of the Scientific Merit Review Panel not to fund CAUT13APS012 was seconded by Ms. Bell.

Discussion: NA

MOTION to approve the recommendation of the Scientific Merit Review Panel not to fund CAUT13APS012 was passed with all in favor.

CAUT13APS015

Dr. Eggerding called for a motion. MOTION by Dr. Evans to approve the recommendation of the Scientific Merit Review Panel not to fund CAUT13APS015 was seconded by Ms. Goldfarb.

Discussion: The applicant was encouraged to rethink the application and reapply considering the opportunity to start small with a pilot project.

MOTION to approve the recommendation of the Scientific Merit Review Panel not to fund CAUT13APS015 was passed with all in favor.

CAUT13APS011

Dr. Eggerding called for a motion. MOTION by Dr. Kansagra to approve the recommendation of the Scientific Merit Review Panel not to fund CAUT13APS011 was seconded by Ms. Bell.

Discussion: A member commented that it was discouraging that the recommendations from the first round were not addressed in the new application.

MOTION to approve the recommendation of the Scientific Merit Review Panel not to fund CAUT13APS011 was passed with all in favor.

CAUT13APS002

Dr. Eggerding called for a motion. MOTION by Mr. Weitzen to approve the recommendation of the Scientific Merit Review Panel not to fund CAUT13APS002 was seconded by Ms. Goldfarb.

Discussion: A member expressed concern about the methodology, specifically taking the children off medications while testing and assumptions that the applicant made about medications.

MOTION to approve the recommendation of the Scientific Merit Review Panel not to fund CAUT13APS002 was passed with all in favor.

CAUT13APS003

Dr. Eggerding called for a motion. MOTION by Ms. Bell to approve the recommendation of the Scientific Merit Review Panel not to fund CAUT13APS003 was seconded by Dr. Evans.

Discussion: Comments included that the study was underpowered and there was no preliminary data.

MOTION to approve the recommendation of the Scientific Merit Review Panel not to fund CAUT13APS003 was passed with all in favor.

V. Report of the Acting Executive Director, Martin T. Zanna, M.D. MPH

Administrative Issues and Website

The Proceedings of the meeting of previously funded basic science and clinical researchers held on March 23, 2012 is in the later stages of development and anticipated to be disseminated within the next 1-2 months once approved by the Department.

Council will select a chairperson at the March 4, 2013 meeting. Please be prepared to make nominations and vote at that time. Dr. Eggerding commented that she would be honored to serve another year; however, if any member would be interested in serving she asked that he/she inform Dr. Zanna.

Update on Council membership. Seven persons have submitted applications for membership on the Council to the Governor's office. Vacant seats include three for academic institutions, one assembly speaker appointee, one public member and individual with family member with autism. Ms. Kirchner commented that Council staff requested an update on the status of the applications.

Dr. Linda Meyer has taken a leave of absence from Autism NJ. Council staff is in contact with Dr. Meyer and the Interim Executive Director Dr. Suzanne Buchanan as we move forward with plans.

Report on RFA and Timeline

On November 5, 2012 the Scientific Merit Review Panel met via teleconference with all 10 members in attendance and reviewed 9 grant applications. Despite the meeting having to be conducted as a conference call instead of an on-site meeting, the process ran smoothly.

Plans to hold the meeting at the Woodbridge Renaissance in Iselin were cancelled due to the hotel being without power and problems encountered at the back-up Hotel (the Trenton, Marriot) resulted in the need to change plans and schedule the conference call.

The decisions made by the Scientific Merit Review Panel were endorsed by the Scientific Advisory Committee (SAC), as described during this evenings discussion of the applications.

Report on the NJ Autism Conference Poster Session

Linda Bocclair attended the Autism NJ meeting in Atlantic City on October 11, 2012 and reported that the posters presented by four Council funded grantees were well received as evidenced by individuals and groups seeking additional information from the researchers. Researchers referred to their posters as they described each aspect of the research including outcomes with the potential to improve the health and well-being of individuals with ASD. Presenters included Dr. Jill Harris (Children's Specialized Hospital), Dr. Gleb Shumyatsky (Rutgers University), Dr. Munjin Kwon for Dr. Bonnie Firestein (Rutgers University) and Dr. Dennis Carmody (UMDNJ-RWJMS).

Report on NJ ACE Grantees

The office is presently working on the annual progress report format for both the NJ ACE Coordinating Center as well as the Program Site. The development incorporates certain aspects of NIH's required annual report as well as NJ ACE specific requirements that will be "built into" the SAGE system. Elements include progress in accomplishing Program Specifications as listed in the Notice of Grant Award(s), including grantees' yearly objectives, methods, timeline and evaluation. The reports will be due in March for review and voting by Council for continuation funding.

Status of FY 13 Research Funding Ad hoc Committee

As mentioned at the September Council meeting, the current RFA process and funding decisions will inform the work of the ad hoc committee and can be included in decisions for funding in FY 14 once the committee reconvenes in early spring. Dr. Eggerding commented on the timeline and appointment of a chairperson for the committee. She stated that it is an important committee looking at translational research, training opportunities and other funding possibilities. It is the intent to have recommendations from that committee in time for funding in FY14. The committee will be reconvened in early spring with final recommendations from the committee to Council in September to inform the cycle to allow funding by June 2014. Dr. Eggerding commented on the need to establish a reasonable RFA cycle – 3 RFAs in a row is too much to expect considering the time it takes to develop the RFAs, set up the SAGE system while providing adequate time for applicants to develop and submit applications.

Continuation Funding for Current Grantees

The current grantees (Coordinating Center and one Program Site) will submit their progress reports in March with Council voting for continuation funding at their May 20, 2013 meeting.

Status of the 2010-2012 Basic Science and Clinical Research Grantees

Nine of the ten grantees have been granted no cost extensions through June 2013. One grant was closed on June 30, 2012. Their final report is being reviewed.

VI. Report of Revenue and Expenditures

Ms. Ray presented the Revenue and Expenditures Report (July 1, 2011 – June 30, 2012). There were no comments or questions from Council.

Mary Ray commented that the Projected Fund Balance will be higher given that only one grant was awarded during tonight's meeting.

Closed Session

Council went into closed session to discuss the release of a new RFA.

After the discussion Dr. Eggerding called for a motion. MOTION to develop an RFA to be funded in FY13 for up to \$6,000,000 to fund Program Sites and/or Pilot Projects was made by Dr. Evans and seconded by Ms. Goldfarb.

MOTION to develop an RFA to be funded in FY13 for up to \$6,000,000 to fund Program Sites and/or Pilot Projects passed with all in favor.

Session re-opened

VII. Adjournment

Dr. Eggerding called for a motion to adjourn. MOTION by Ms. Goldfarb to adjourn was seconded by Dr. Kansagra.

MOTION passed with all in favor. The meeting was adjourned at 8:20 PM.